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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/260,468	03/02/1999	JAMES ROBL	000270 - 057	6587

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/260,468	ROBL ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,13-19,24-30,32-38,40-52 and 58-60* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,13-19,24,25,32-38,40-52 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed March 2, 1999, is a continuation in part of 09/032,945, filed March 2, 1998, now abandoned, which is a continuation in part of 08/699,040, filed August 19, 1996, now abandoned.

Applicants amendment filed April 28, 2005 has been received and entered. Claims 1, 2, 4, 5, 8-10, 13, 15, 16, 18, 19,, 32, 36-38, 40, 41, 43, 46 -50 and 60 have been amended. Claims 3, 12, 20-23, 31, 39, 53-57, and 61 has been canceled. Claims 1, 2, 4-11, 13-19, 24-30, 32-38, 40-52, 58-60 are pending.

Examiner's comment

It is noted that the present claim listing again is not in compliance with 37 CFR 1.121. For example, claims 18 and 19 have the status identifier of (currently amended), however there are not editor marks in the claim indicating the changes to the claims. It is noted that word for word comparison of the present claim set and that previously submitted has not been done by the examiner to identify other possible problems, however after Applicants two attempts to become in compliance with 37 CFR 1.121, Examiner has decided accept and examine the present clam set as presented to advance prosecution.

Election/Restrictions

Claims 1, 2, 4-11, 13-19, 24-30, 32-38, 40-52, 58-60 are pending. Claims 26-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 24, 2000 (see paper number 8). Claims 1, 2, 4-11, 13-19, 24, 25, 32-38, 40-52, 58-60 are currently under examination.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 19 objected to under 37 CFR 1.75 as being a substantial duplicate of claims 21-23 is withdrawn.

Claims 21-23 have been cancelled.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-11, 13-19, 24, 25, 32-38, 40-52, 58-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34, 35-58 of copending Application No. 09/467,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims under examination in both applications both encompass methods of cross-species nuclear transfer using conventional methodology and the products produced from those methods. The claims of '076 are specifically drawn to the use of ungulates, however the present claims encompass this by specifically setting forth the production of any form of an embryonic or stem-like cell, by the recitation of the use of any mammalian cell nucleus including ungulate/bovine (claims 49 and 50) and the recipient cell is an oocyte from ungulates/bovine (claims 6 and 7).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 4-11, 13-19, 24, 25, 32-38, 40-52, 58-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34, 35-58 of copending Application No. 10/329,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims under examination in both applications both encompass methods of cross-species nuclear transfer using conventional methodology and the

products produced from those methods. In the instant case, the claims differ from the present claims in the recitation and use of "or cell nucleus", instead of only the use of a cell. In this case this is an obvious variation since the what is required in the transfer and what remains in the resulting nuclear transfer unit is the nucleaus of the donor cell.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-11, 13-19, 24, 25, 32-38, 40-52, 58-60 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants note the amendment to the claims and point to the support for the amendment in the specification and request removal of the rejection. See Applicants' amendment, top of page 11. Applicants' arguments have been fully considered, but not found persuasive.

The amendments to the claims are noted however they fail to address the basis for the enablement rejection, in particular the ability to successfully culture such a NT unit beyond a given cell number, nor the ability to isolate or derive embryonic stem like cells

from such a cultured NT unit. It is noted that dependent claims are drawn to and encompass the cells generated by this method and uses of these cells in therapeutic methods which each have specific points of lack of enablement recognized in the art that are not remedied by the instant specification. In support of the rejection Examiner has cited Wolfe et al. (Theriogenology, 3341):350, 1990) who teach that the affects of intergeneric nuclear transplantation was studied and that species more distant from the cow were less capable of supporting growth and differentiation of the resulting NT unit, and more broadly reviewed byGurdon (J. Cell Sci 4:287-318, 1986) who teaches that species as distant as human and Xenopus have been tested by nuclear transfer and while capable of supporting several cell divisions, is always lethal usually arresting at an irregular blastulae (page 300). While Wolfe et al. and Gurdon do not specifically teach what causes the arrest in development, Meirelles et al. (Genetics 158:351-356) teach that while mitochondrial heteroplasmy may occur in systems with related nuclear and mitochondrial DNA, even unrelated species of Bovus do not support the full development of a nuclear transfer unit generated by more distant species. A more recent review by Dominko et al. (Biol of Reprod 60:1496-1502, 1999) provides a even more generally review for the use of distant mammalian species clearly teaching the necessity of testing the compatibilities of cytoplasmic (i.e. mtDNA) and nuclear DNA when practicing interspace NT (see summary on page 1501). Therefore, based on the art of record only species with closely related nuclear and cytoplasmic genes would be capable of successfully reconstituting the genetic complement necessary for development of an embryo (see surnmary in abstract). Moreover, the simple reliance of the instant specification on nuclear transfer methodology known in the art fails to address even such

limitations of successfully practicing intra-species nuclear transfer (see for example Aronson et al. (Current Topics in Devolopmental Biology 23: 55-71). Moreover, the art teaches that embryonic stem cells from the broad range of animals encompassed by the instant claims encompassed by the claims have not been successfully isolated from normal embryos. The present specification provides no further guidance providing the necessary methodology required to isolate embryonic stem cells beyond those readily known in the art. ln summary, while the methods of inserting the nuclear material from one species into the oocyte of another different species was known and practiced at the time of the claimed invention, the methodology to successfully culture the resulting NT unit into a blastocyst from which ES cells could be obtained was not successfully practiced. The instant specification relies in great part on the teaching in the art to practice nuclear transfer methodology and fails to address art recognized shortcomings for successfully culturing transpecies NT unit cells from distantly related species. Further, lacking the ability to obtain a viable NT unit capable of forming a viable embryo containing embryonic stem cells, the specification fails to provide the necessary guidance to isolate and culture embryonic stem cells from species from which embryonic stem cells have not been derived. With respect to the working examples provided in the present specification for cell culture obtained from introducing human nuclear material into a cow embryo, as indicated in the previous office action the morphological characterization of the resulting cells is insufficient to establish that the cells are in fact embryonic stem cells. Consistent with this view subsequent peered reviewed articles have questioned the lack of substantive data support for the instant claims (Science 282:1390-1391, 1998).

The claims are directed to a method for the production of human or mammalian embryonic or stem-like cells comprising; inserting a differentiated human or mammalian cell or nucleus into an enucleated oocyte from a different animal species than the human or mammalian cell forming a NT unit; activating the NT unit; inserting cytoplasm into the oocyte from the same species of animal as the donor cell or nucleus; culturing the activated NT unit into cells; and culturing the cells to obtain embryonic or stem-like cells. Further, embodiments include, differentiating or genetically modifying the resulting embryonic or stem-like cells. The claimed invention is further directed to the products produced by said methods. The specification discloses the preparation of nuclear transfer units using a method of nuclear transfer of adult human epithelial cell nucei into enucleated bovine oocyte to form a nuclear transfer (NT) unit by electrofusion techniques. The method disclosed in Example 1 of the specification result in the production of a NT unit (16-400 cell stage) according to Table 1, page 64. Although the methods of the instant invention result in the production of a NT unit of which Applicants report propagates into what appears to be ES-like cell colonies (as determined by cell morphology); Applicants fail to demonstrate that the ES-like cells ftinction as true ES-cells in that they are in fact totipotent or that they function as stem cells in that they are capable of differentiation into other multilineage cell-types. As such, Applicants fail to enable the production of embryonic or stem-like cells. Again, the unpredictability of the method of NT transfer, as a whole, lies in the need to convert a differentiated cell to a totipotent cell (embryonic stem cell). Cells contain the same DNA complement, however, in differentiated tissues, not all DNA sequences are expressed. For example, a liver does not make rhodopsin and retinal cell structures, and retinal cells do not make clotting

factors and hepatocyte structures. For a cell to go through all the steps of development, it, or its nucleus, must be reverted to the stage where all DNA sequences can potentially be expressed, and expression regulated according to developmental stage. Applicants have not provided evidence that the cells produced by their methods are true pluripotent cells (embryonic stem cells or embryonic or stem-like cells). Applicants fail to demonstrate whether their ES-like cells stain positive for alkaline phosphatase (AP), exhibit the formation of embryoid bodies, spontaneously differentiate into at least two different cell type, or express ES cell markers. Applicants only disclose several morphological characteristics (Example I, page 62).

Therefore, in view of art of record it would have required undue experimentation to determine the parameters listed above, the lack of direction and/or guidance provided by the specification, the absence of working examples for the demonstration of or reasonable correlation to producing human or mammalian embryonic or stem-like cells capable of mere differentiation, for example, the unpredictability and undeveloped state to the art with respect to cross species nuclear transfer (using adult differentiated nuclei) for production of embryonic stem cells which give rise to germline tissue and the whole animal or which may be induced to differentiate, in particular with respect to carrying out a process involving insertion of differentiated, adult human cell nuclei into bovine oocytes, the unpredictable state of the art with respect to extrapolating results obtained from ES cells of different species of animals to results obtained from chimeric bovine/human embryonic or stem-like cells.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made,

it would have required undue experimentation to make and/or use the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 18, 19, 51 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradley et al. (Biotechnology, 1992).

Claims 18, 19, 51 and 59 encompass to embryonic or stem-like cells. It should be noted that the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). This is because the final product (the embryonic or stem-like cells) is not distinguished by any particular features or characteristics as a result of the process by which it is made. As such, the limitations of the claimed cells are met by any embryonic or stem-like cell in the prior art. Bradley *et al.* teach mouse embryonic stem cell lines ABI, AB2.1, and CCE, which display germline transmission. Accordingly, Bradley *et al.* clearly anticipate the claimed products.

Claims 18, 19, 51 and 59 are rejected under 35 U.S.C. 102(a) as being anticipated by Granerus *et al.* (Cell Proliferation, 1996).

The claims are directed to human embryonic or stem-like cells. Note that it is only the product which is anticipated by the prior art and not the process by which the product is made. This is because the final product is not distinguished by any particular features or characteristics as a result of the process by which it is made. As such, the limitations of the claimed cells are met by any embryonic or stem-like cell in the prior art. As such, note that it is not clear as to what the phrase "human embryonic or stem-like cells" encompasses. Granerus *et al.* disclose a human cell line, Tera 2, which functions in several aspects as a human embryonic stem cell (see summary in abstract). Thus, without a distinguishing structural or functional difference of the claimed cells, the human cells of Granerus *et al.* haveing embryonic stem cell activity meet all of the limitations of the claimed cells. Accordingly, Graneus *et al.* clearly anticipate the claims.

Claims 18, 19, 51 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsukamoto *et al.* (US Patent 5,716,827).

The claims are directed to human embryonic or stem-like cells and to a mammalian somatic cell that expresses DNA that encodes a detectable marker linked to a particular cyclin. In this case, any cell containing and expressing a cyclin would anticipate the claim. Note that it is only the product which is anticipated by the prior art and not the process by which the product is made. This is because the final product is not distinguished by any particular features or characteristics as a result of the process by

which it is made. As such, the limitations of the claimed cells are met by any embryonic or stem-like cell in the prior art. Tsukamoto *et al.* teach the production of human hematopoietic stem cell capable of producing members of each of the hematopoietic lineages, that is differentiated cells (see abstract and claims 1 and 2). Thus, without a distinction indicating a structural or functional difference of the claimed cells, the human hematopoietic cells and differentiated cells produced therefrom taught by Tsukamoto *et al.* meet all of the limitations of the claimed cells. Accordingly, Tsukamoto *et al.* clearly anticipate the claimed invention.

Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamane (Japanese Journal of Cancer and Chemotherapy, 1987).

Note that the same product-by-process analysis is applied here as in the preceding rejections. In this case the claims encompass differentiated cells. Yamane disclose human differentiated cells derived from epithelial cells, skin keratinocytes and endothelial cells (see summary in abstract). Thus, without any distinction indicating a structural or functional difference of the claimed cells, the human differentiated cells of Yamane meet all of the limitations of the claimed cells.

Accordingly, Yamane clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-11, 13-19, 24, 25, 32-38, 40-52, 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfe *et al.* (Theriogenology, 1990), Collas *et al.* (Molecular Reproduction and Development, 1994) and Westhusian *et al.* (Theriogenology, 1996).

It is noted that the claims have been amended so not to require mtDNA and different nuclear DNA, and resemble the claims as originally presented. The claims are directed to a method of producing human embryonic or stem-like cells via nuclear transfer of a differentiated human or mammalian cell nucleus to an animal oocyte. Wolfe *et al.* teach a method of cross-species nuclear transfer using nuclei from bovine preimplantation embryos and oocytes of a varying species. Wolfe *et al.* disclose the production of blastocysts derived from bovine nuclei and bison ovum as well as bovine nuclei and goat ovum. Thus, the experimentation of Wolfe *et al.* demonstrates that mammalian nuclei may becapable of interacting with cytoplasm from other mammalian species to support normal development (see summary in Abstract). Wolfe *et al.* do not propose nuclear transfer of human or mammalian differentiated nuclei into bovine oocytes, however, at the time the claimed invention was made, Collas *et al.* disclose results indicating that transplanted differentiated nuclei may be pluripotent. Collas *et al.*

also suggest that "a variety of differentiated mammalian cell types may promote early preimplantation development of NT embryos." (page 266, Discussion section). Accordingly, in view of the collective cited prior art, it would have been *prima facie* obvious for one of ordinary skill in the art to select human or mammalian differentiated cell nuclei and animal oocytes of a varying species for use in nuclear transfer with a reasonable expectation of producing at least one nuclear transfer unit of which is capable of being cultured into cells which meet the limitation of "embryonic or stem-like" cells. Further, at the time of the claimed invention, it was recognized that the various methods for nuclear transfer had technical drawbacks which reduced the efficiency of the methodology. Westhusin *et al.* teach that one such limitation occurs during the process of enucleating the oocyte when ovum cytoplasm is removed (page 244; fourth column). Further, Westhusin *et al.* note that their experiments and those of others clearly indicate that the cytoplasm/nuclear ratio plays an important role in embryonic development, where reduced levels of cytoplasm results in a significant effect on embryo survival (page 244; first column). In view of their results and that reported by others, Westhusin *et al.* conclude that a reduction in the amount of cytoplasm affects the number of cells in the morula and blastocyst, affects embryo quality, and may affect later embryo development (page 248; beginning of discussion section). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to control the amount of cytoplasm during the procedure of nuclear transfer. As noted by Westhusin *et al.* many of the nuclear transfer procedures result in the loss of cytoplasm, so one of ordinary skill in the art would have been motivated, in view to the work of Westhusin *et al.* to include the addition of cytoplasm to the NT unit. In addition, it is also

noted that the cytoplasm/nuclear ratio is an important factor in the survivability of the embryo, thus, the artisan would have been further motivated to control the cytoplasm/nuclear ratio by the addition of cytoplasm during the nuclear transfer procedure which was lost during enucleation. There would have been a reasonable expectation of success given the state of art and that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. 103, all that is required is a reasonable expectation of success. See *In re O'Farrell* 7USPQ2d 1673 (CAFC 1988).

Thus, the claimed invention, as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AU1632